



DEPARTMENT OF COMMERCE
UNITED STATES Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

Seng

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/550,857 04/17/00 BUCH-RASMUSSEN

T NN 26

HM12/1106

ROBERT B SMITH
SKADDEN ARPS SLATE MEAGHER & FLOM LLP
FOUR TIMES SQUARE
NEW YORK NY 10036

EXAMINER

FONDA, K

ART UNIT

PAPER NUMBER

1623

DATE MAILED:

11/06/01

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/550,857

Applicant(s)
Buch-Rasmussen et al.

Examiner
Kathleen Kahler Fonda

Art Unit
1623



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 17, 2001
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above, claim(s) 56-58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

Art Unit: 1623

Applicant's election with traverse of Group I, claims 1-55 in Paper No. 9 is acknowledged. The traversal is on the ground(s) that the combination and subcombination are not restrictable. This is not found persuasive because, as set forth in the restriction requirement, the two inventions represent mutually exclusive species in intermediate-final product relationship, and are not obvious variants.

The requirement is still deemed proper and is therefore made FINAL.

Applicant is required to amend the specification to include a Brief Description of the Drawings. Also, if photographs are to be used as formal drawings, Applicant's attention is drawn to 37 CFR 1.84. Photographs and color drawings are acceptable only for examination purposes unless a petition filed under 37 CFR 1.84(a)(2) or (b)(1) is granted permitting their use as formal drawings. Any such petition must be accompanied by the appropriate fee as set forth in 37 CFR 1.17(h) and, if filed under the provisions of 37 CFR 1.84(a)(2), an amendment to the first paragraph of the brief description of the drawings section of the specification which states:

The file of this patent contains at least one drawing executed in color. Copies of this patent with color

Art Unit: 1623

drawing(s) will be provided by the Patent and Trademark Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings have been satisfied. Applicant's attention is also drawn to the May 1, 1998 waiver of 37 C.F.R. 1.84(b)(1)(ii) to the extent that the submission of a single set (as opposed to three sets) of black and white photographs will be considered acceptable upon the filing of a petition under 37 C.F.R. 1.84(b)(1). If color photographs are submitted, three sets are still required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claim 1 is indefinite because the language "solid pharmaceutical composition for parenteral injection" does not clearly convey that the composition is to be injectable without prior dissolution or other reconstitution.

Art Unit: 1623

Claim 20 is indefinite because the scope of "a derivative thereof" is not certain.

Claim 26 is indefinite because the term "alcohols" rather than -alcohol-- calls into question how many different non-crystallisation agents are required in each composition.

Claim 29 lacks positive antecedent basis for "the temperature interval" and is therefore indefinite.

The term "preferably" in claim 35 renders the claim indefinite because it is not clear whether the claim is intended to encompass only the preferred embodiment or not. Also, the term "derivatives" renders the claim indefinite because the scope is uncertain.

Claim 36 is indefinite because it is not clear what kind of "stability" (to heat, light, oxidation, etc.) is not to be reduced.

Claim 40 is indefinite because "Tg" should be accompanied by its meaning in parenthesis the first time it is used in an independent claim. Furthermore, --and-- should precede the final optional step of the claim.

Claim 43 is indefinite because it is not clear from the term "preferentially" whether the claim is intended to encompass only the preferred embodiment or not.

Art Unit: 1623

Claim 48 is indefinite because there is no positive antecedent basis for "the temperature interval."

Claim 53 is indefinite because the phrase "including man" is a specific within a generic and thus calls the intended scope of the claim into question.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 52 is are rejected under 35 U.S.C. 102(b) as being anticipated by ROSER *et al.* (B2). Pages 6-7 teach that solid compositions as claimed may be injected through the skin.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

Art Unit: 1623

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over ROSER *et al.* (B2).

Applicant claims solid pharmaceutical compositions for parenteral injection which contain a carbohydrate binder and optionally, a non-crystallisation agent. The composition may be formulated to withstand penetration of the epidermis. Applicant also claims method of making the compositions by mixing, shaping, and cooling. Finally, Applicant claims a method of injecting a solid pharmaceutical composition using an ejection device.

Art Unit: 1623

RODER teaches a solid dose delivery system comprising an active agent and a glassy vehicle which may be a carbohydrate. Roder furthermore teaches inclusion of sugar alcohols, which are non-crystallisation agents of the claims. The composition may be formulated in various shapes, including as a needle. Any of a number of therapeutic agents may be employed. See the claims. The Roder method or preparation (see e.g. claim 43) includes mixing, shaping, and drying. Pages 6-7 of Roder suggest administration to animals as well as human patients.

RODER does not specifically state that the therapeutic agent should consist of at least one dosage form. In addition, Roder may not explicitly disclose each of the ingredients or formulation details as claimed.

It would have been obvious for a person of ordinary skill in the art at the time of the invention to include at least one dosage form, for the purpose of providing effective treatment for the patient. All of the ingredients as claimed are suggested by Roder, and thus it would have been obvious to include them. The formulation details are considered to have been obvious in view of the overall teaching of Roder, for the purpose of optimizing the effectiveness of the composition.

No claim is allowed.

Art Unit: 1623

Papers relating to this application may be submitted to Technology Center 1600 by facsimile transmission. The number of the fax machine for official papers in Technology Center 1600 is (703) 308-4556. Any document submitted by facsimile transmission will be considered an official communication unless the cover sheet clearly indicates that it is an informal communication.

INTERNET INFORMATION: Secure and confidential access to patent application status information is now available; see <http://www.uspto.gov/ebc/index.html> for more information. Also, <http://www.uspto.gov/web/offices/ac/comp/fin/clonedefault.htm> may be used to pay patent maintenance fees, pay non-filing application fees, and maintain USPTO deposit accounts.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Kathleen Kahler Fonda, at telephone number (703) 308-1620. Examiner Fonda can generally be reached Tuesday through Friday, and on alternating Mondays, from 7:30 a.m. until 5:00 p.m. If the Examiner cannot be reached, questions may be addressed to Supervisory Patent Examiner Gary Geist at (703) 308-1701. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-1235.

Kathleen Kahler Fonda, Ph.D.
Primary Examiner
Art Unit 1623

